



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Peter Soukas, J.D., 301-496-2644; [peter.soukas@nih.gov](mailto:peter.soukas@nih.gov). Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases (NIAID), 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

#### **Expression of Prefusion-stabilized Spike S Glycoprotein of SARS CoV-2 from Avian Paramyxovirus Type 3 (APMV3).**

##### **Description of Technology:**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged in 2019 as the causative agent of coronavirus disease 2019 (COVID-19) and has created a pandemic and global crisis in public health. Vaccines for SARS-CoV-2 are increasingly available under emergency use authorizations; however, authorizations for use are currently limited

to individuals five (5) years or older. They also involve intramuscular immunization, which does not directly stimulate local immunity in the respiratory tract, the primary site of SARS-CoV-2 infection, shedding and spread. Ideally, a vaccine should be effective as a single dose and should induce systemic and mucosal immunity with the ability to restrict SARS-CoV-2 infection and respiratory shedding.

The application relates to a live virus-vectored intranasal vaccine candidate to prevent infection and transmission of SARS-CoV-2. Avian paramyxovirus type 3 (APMV3) was used as a vaccine vector to express the spike (S) protein stabilized in prefusion conformation by six proline substitutions (APMV3/S-6P). The S protein was from the first available SARS-CoV-2 sequence. A lack of pre-existing immunity in humans and attenuation by host range restriction make APMV3 a vector of interest. Unlike avian paramyxovirus 1 (Newcastle Disease Virus), APMV3 is not a significant pathogen in poultry. The APMV3/S-6P vaccine is expected to induce durable and broad systemic and respiratory mucosal immunity against SARS-CoV-2. In the hamster model, a single intranasal dose of APMV3/S-6P induced a strong serum neutralizing antibody response to the vaccine-matched SARS-CoV-2 isolate WA1, and a strong serum IgG and IgA response to S protein and its receptor-binding domain. Serum antibodies of APMV3/S-6P-immunized hamsters effectively neutralized SARS-CoV-2 of lineages B.1.1.7 (Alpha) and B.1.351 (Beta). Immunized hamsters challenged with SARS-CoV-2, strain WA1, did not exhibit weight loss and lung inflammation, and SARS-CoV-2 replication in the upper and lower respiratory tract was low or undetectable. Thus, a single intranasal dose of APMV3/S-6P fully protected hamsters from SARS-CoV-2 challenge, suggesting that APMV3/S-6P is suitable for clinical development.

Based on experience with this and other live-attenuated virus-vectored vaccine candidates in previous clinical studies, the present candidate is anticipated to be well-tolerated in humans. The National Institute of Allergy and Infectious Diseases has

extensive experience and capability in evaluating live-attenuated respiratory virus vaccine candidates in pediatric clinical studies, and opportunity for collaboration exists.

This technology is available for nonexclusive licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

**Potential Commercial Applications:**

- Viral diagnostics
- Vaccine research

**Competitive Advantages:**

- Ease of manufacture
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

**Development Stage:**

- *In vivo* data assessment (animal)

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**Intellectual Property:** HHS Reference No. E-238-2020-0 - U.S. Provisional Application No. 63/280,884, filed November 18, 2021

**Licensing Contact:** Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

**Collaborative Research Opportunity:** The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-496-2644; peter.soukas@nih.gov.

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